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10/562,085	03/02/2007	Bernard Verrier	033339/305755	9648

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EXAMINER	
THOMAS, TIMOTHY P	
ART UNIT	PAPER NUMBER
1614	
MAIL DATE	DELIVERY MODE
07/21/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/562,085	VERRIER ET AL.	
	Examiner	Art Unit	
	TIMOTHY P. THOMAS	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 April 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2 and 4-10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2 and 4-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. Applicants' arguments, filed 4/20/2009, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

2. The amendment to claim 8, removing the redundant reference to the second concentration range renders the claim objection to claim 8 moot. Therefore, the objection is withdrawn.

3. Applicant's arguments with respect to the rejection under 35 USC 112, 2nd paragraph have been fully considered but they are not persuasive:

Claim 10 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The shift of this rejection to claim 10 is necessitated by the amendment adding this new claim. The rejection is withdrawn from claim 8, based on the claim amendment.

The claim recites "a concentration of between 10 mg/kg to 1 g/kg". It is not clear whether this amount refers to a concentration in a liquid solution (or solid composition) or alternatively to a dosage, such as 10 mg of the alcohol is dosed per kg of subject body weight, since mg/kg are units commonly used in the art to describe an amount dosed to a patient in terms of a drug amount (in mg)

per body weight (in kg); however, this view is confused by the term "concentration", which generally refers to the relative amount of an active ingredient in a composition. It is assumed for the purposes of prior art determinations that the latter is the meaning of the claim (i.e., that the concentration is with respect to the alcohol in a composition that is administered

4. Applicant's arguments, see p. 8, filed 4/20/2009, with respect to the rejection(s) of claim(s) 2, 4-7 and 9 under 35 U.S.C. 103(a) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made which is outlined below.

The rejection is withdrawn based on the amendment to claim 9, changing "comprising" to "consisting of", and applicant's argument that this language excludes DNase.

Claim Objections

5. Claim 7 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

This objection is necessitated by the claim amendment.

Claim 9 has been amended to use the transition language "consisting of". This claim now requires the step of administration of one or more linear n-alkanols, but excludes other components being administered, including a carrier.

Dependent claim 7 recites that said n-alkanols are combined with at least one carrier, which expands, rather than limits the scope of the independent claim.

6. Claim 10 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 8. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

This objection is necessitated by the claim amendment adding new claim 10.

Claim 8 and 10 are identical in scope, when the "concentration" is construed to mean the amount of n-alkanol in a composition that is administered. The ratios of masses in claim 10 would give identical values in terms of ppm, since the "parts" have a linear relationship to mass, therefore the ratio renders the amounts the same.

Claim Rejections - 35 USC § 102/103

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. Claims 2 and 4-10 are rejected under 35 U.S.C. 102(e) as anticipated by Vail, III et al. (US 7,150,888 B1; 2006; filed 2002 Sep; priority 2000, 2001, 2002) as evidenced by Swords et al. ("Composition of Australian Tea Tree Oil (Melaleuca alternifolia)"; 1978; Journal of Agricultural Food Chemistry; 26(3): 734-737); or, in the alternative, under 35 U.S.C. 103(a) as obvious over Vail, III et al. (US 7,150,888 B1; 2006; filed 2002 Sep; priority 2000, 2001, 2002) in view of Swords et al. ("Composition of Australian Tea Tree Oil (Melaleuca alternifolia)"; 1978; Journal of Agricultural Food Chemistry; 26(3): 734-737).

This rejection is necessitated by the claim amendment to 9 and applicant's arguments that the language excludes combinations of an alcohol with other active ingredients. It is noted that since dependent claim 7 specifically recites the

presence of a carrier, but the independent claim 9 excludes a carrier, both embodiments (with and without a carrier) are addressed below.

Vail teaches strong vapors from eucalyptus oil and/or tea tree oil are inhaled periodically to prevent respiratory system diseases including opportunistic infections in individuals having cystic fibrosis (abstract; col. 1, lines 63-66); Austrialian Tea Tree Oil, made by Desert Essence was inhaled, from 0.001-100 mg per nostril (col. 5, lines 34-37, 49-50); inhalation by mouth or nose (col. 5, line 60; col. 6, line 20); vapors are generated by an atomizer (produces a nebulized material (col. 6, lines 4-9); the liquid used to form a vapor is pure tea tree oil or one or more components from tea tree oil (col. 9, lines 65-67) or one or more components of tea tree oil with distilled water (water would be a carrier appropriate for intranasal administration; col. 10, lines 5-7); the components of tea tree oil include hexanol (a 1-position alcohol) according to the Swords reference (col. 14, lines 40, 46 of Vail).

Swords teaches the composition of Austrailian Tea Tree Oil (title); the compounds identified include Hexanol at a trace amount (p. 737, Table I, #14; corresponding to the gas chromatogram peak 14 of Figure 1, p. 734); the lowest amount identified numerically that is above a "trace" amount is for peak 18 (α-Cubene), which has a percent of 0.04% (p. 737, Table I); a relevant portion of Figure 1 is expanded here for discussion:

Consideration of the relative sizes of peak 18 and peak 14 (corresponding to hexanol), peak 14 looks to be about 1/10 the size of peak 18. Although not quantitative, this amount would provide an estimate for the amount of hexanol in the Tea Tree Oil of 1/10 of 0.04%, or about 0.004% (which corresponds to about 40 ppm or 40 mg/kg of the composition administered). Therefore, the administration of Tea Tree Oil to a patient with cystic fibrosis would meet the required amounts of claim 8 and 10, if the claims are construed in the manner that the "at least" in claim 9 allows for the additional components in the Tea Tree Oil. With respect to the required "amount" sufficient to generate in the vicinity of said epithelial cell membranes of a patient with cystic fibrosis a concentration of hexanol sufficient to open the CFTR in the cell membrane, required by claim 9, the administration of an amount specifically within the concentrations of claims 8 and 10 via intranasal as an aerosol, as specifically recited in claims 5-7 would be expected to provide the same result.

It is noted that In re Best (195 USPQ 430) and In re Fitzgerald (205 USPQ 594) discuss the support of rejections wherein the prior art discloses subject matter which there is reason to believe inherently includes functions that are

newly cited or is identical to a product instantly claimed. In such a situation the burden is shifted to the applicants to "prove that subject matter shown to be in the prior art does not possess characteristic relied on" (205 USPQ 594, second column, first full paragraph).

Alternatively, if, as applicant argues, the claims are construed in such a manner that other components of Tea Tree Oil are excluded from the administration step, then the combination of Vail and Swords renders the methods of the claims as obvious. Prevention of opportunistic infections or treating such infections in cystic fibrosis is the topic of Vail. Since Vail clearly indicates that components of Tea Tree Oil (hexanol is taught to be one such component) or such components with water as a carrier may be administered via the vapor producing device, it would have been obvious to administer hexanol or hexanol in a carrier water (required by claim 6) in a liquid for administration in the form of a nebulized material orally or nasally to a patient with cystic fibrosis, as clearly taught by Vail. It would have also been obvious to optimize the amounts, increasing from 0.004% to a larger amount that is effective in reducing opportunistic infections in the patient, giving the methods of the instant claims. The motivation would have been the routine optimization of conditions. Considering the the instant specification indicates opportunistic bacterial infections are caused by thickening of the extracellular mucus which leads to obstructions in the lumens of the tissues, such optimization would result in administered amounts that would achieve the local concentration required by claim 9, absent evidence to the contrary.

Conclusion

11. No claim is allowed.

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TIMOTHY P. THOMAS whose telephone number is (571)272-8994. The examiner can normally be reached on Monday-Thursday 6:30 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Timothy P Thomas/
Examiner, Art Unit 1614

/Ardin Marschel/
Supervisory Patent Examiner, Art Unit 1614